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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Supplemental
Notice of Allowability**

Application No.

10/052,386

Examiner

Robert B. Mondesi

Applicant(s)

SAKSENA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 23, 2005.
2. ☒ The allowed claim(s) is/are 1-51, 62-67, ~~98~~ 107.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Authorization for this examiner's amendment was given in a telephone interview with Harvey Cohen on August 29, 2005.

In the claims:

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Formula I

Y is selected from the group consisting of the following moieties: alkyl, alkyl-aryl, heteroalkyl, heteroaryl, aryl-heteroaryl, alkyl-heteroaryl, cycloalkyl, alkyloxy, alkyl-aryloxy, aryloxy, heteroaryloxy, heterocycloalkyloxy,

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cycloalkyloxy, alkylamino, arylamino, alkyl-arylamino, arylamino, heteroarylamino, cycloalkylamino and heterocycloalkylamino, with the proviso that Y maybe optionally substituted with X^{11} or X^{12} ;

X^{11} is alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkyl-alkyl, heterocyclyl, heterocyclylalkyl, aryl, alkylaryl, arylalkyl, heteroaryl, alkylheteroaryl, or heteroarylalkyl, with the proviso that X^{11} may be additionally optionally substituted with X^{12} ;

X^{12} is hydroxy, alkoxy, aryloxy, thio, alkylthio, arylthio, amino, alkylamino, arylamino, alkylsulfonyl, arylsulfonyl, alkylsulfonamido, arylsulfonamido, carboxy, carbalkoxy, carboxamido, alkoxycarbonylamino, alkoxycarbonyloxy, alkylureido, arylureido, halogen, cyano, or nitro, with the proviso that said alkyl, alkoxy, and aryl may be additionally optionally substituted with moieties independently selected from X^{12} ;

R^1 is COR^5 or $B(OR)_2$, wherein R^5 is NR^9R^{10} , CF_3 , C_2F_5 , C_3F_7 , CF_2R^6 , R^6 , or COR^7 wherein R^7 is H, OH, OR^8 , CHR^9R^{10} , or NR^9R^{10} , wherein R^6 , R^8 , R^9 and R^{10} are independently selected from the group consisting of H, alkyl, aryl, heteroalkyl, heteroaryl, cycloalkyl, cycloalkyl, arylalkyl, heteroarylalkyl, $[CH(R^{1'})]_pCOOR^{11}$, $[CH(R^{1'})]_pCONR^{12}R^{13}$, $[CH(R^{1'})]_pSO_2R^{11}$, $[CH(R^{1'})]_pCOR^{11}$, $[CH(R^{1'})]_pCH(OH)R^{11}$, $CH(R^{1'})CONHCH(R^{2'})COO R^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})R'$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})COO R^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})COO R^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})CONHCH(R^{5'})COO R^{11}$ and

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$\text{CH}(\text{R}^{1'})\text{CONHCH}(\text{R}^{2'})\text{CONHCH}(\text{R}^{3'})\text{CONHCH}(\text{R}^{4'})\text{CONHCH}(\text{R}^{5'})\text{CONR}^{12}\text{R}^{13}$,
wherein $\text{R}^{1'}$, $\text{R}^{2'}$, $\text{R}^{3'}$, $\text{R}^{4'}$, $\text{R}^{5'}$, R^{11} , R^{12} , and R^{13} , ~~and R^{14}~~ are
independently selected from the group consisting of H, alkyl,
aryl, heteroalkyl, heteroaryl, cycloalkyl, alkyl-aryl, alkyl-
heteroaryl, aryl-alkyl and heteroaralkyl;

Z is selected from O, N, CH or CR;

W may be present or absent, and if W is present, W is
selected from C=O, C=S, C(=N-CN), or SO₂;

Q may be present or absent, and when Q is present, Q is CH,
N, P, (CH₂)_p, (CHR)_p, (CRR')_p, O, NR, S, or SO₂; and when Q is
absent, M may be present or absent; when Q and M are absent, A
is directly linked to L;

A is O, CH₂, (CHR)_p, (CHR-CHR')_p, (CRR')_p, NR, S, or
SO₂;

E is CH, N, CR, or a double bond towards A, L or G;

G may be present or absent, and when G is present, G is
(CH₂)_p, (CHR)_p, or (CRR')_p; and when G is absent, J is present
and E is directly connected to the carbon atom in Formula I as G
is linked to;

J may be present or absent, and when J is present, J is
(CH₂)_p, (CHR)_p, or (CRR')_p, SO₂, NH, NR or O; and when J is
absent, G is present and E is directly linked to N shown in
Formula I as linked to J;

L may be present or absent, and when L is present, L is CH,
CR, O, S or NR; and when L is absent, then M may be present or
absent; and if M is present with L being absent, then M is
directly and independently linked to E, and J is directly and
independently linked to E;

M may be present or absent, and when M is present, M is O,
NR, S, SO₂, (CH₂)_p, (CHR)_p, (CHR-CHR')_p, or (CRR')_p;

p is a number from 0 to 6; and

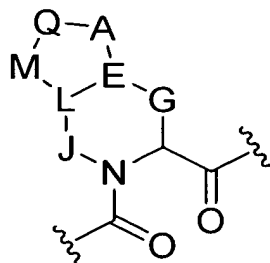
R, R', R², R³ and R⁴ are independently selected from the group consisting of H; C₁-C₁₀ alkyl; C₂-C₁₀ alkenyl; C₃-C₈ cycloalkyl; C₃-C₈ heterocycloalkyl, alkoxy, aryloxy, alkylthio, arylthio, amino, amido, ester, carboxylic acid, carbamate, urea, ketone, aldehyde, cyano, nitro, halogen; (cycloalkyl)alkyl and (heterocycloalkyl)alkyl, wherein said cycloalkyl is made of three to eight carbon atoms, and zero to six oxygen, nitrogen, sulfur, or phosphorus atoms, and said alkyl is of one to six carbon atoms; aryl; heteroaryl; alkyl-aryl; and alkyl-heteroaryl;

wherein said alkyl, heteroalkyl, alkenyl, heteroalkenyl, aryl, heteroaryl, cycloalkyl and heterocycloalkyl moieties may be optionally and chemically-suitably substituted, with said term "substituted" referring to optional and chemically-suitable substitution with one or more moieties selected from the group consisting of alkyl, alkenyl, alkynyl, aryl, aralkyl, cycloalkyl, heterocyclic, halogen, hydroxy, thio, alkoxy, aryloxy, alkylthio, arylthio, amino other than for R², amido, ester, carboxylic acid, carbamate, urea, ketone, aldehyde, cyano, nitro, sulfonamido, sulfoxide, sulfone, sulfonyl urea, hydrazide, and hydroxamate;

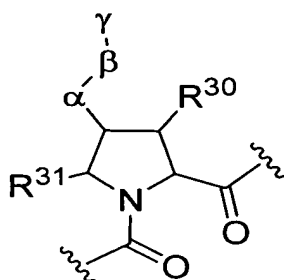
further wherein said unit N-C-G-E-L-J-N represents a five-membered or six-membered cyclic ring structure with the proviso that when said unit N-C-G-E-L-J-N represents a five-membered cyclic ring structure, or when the bicyclic ring structure in Formula I comprising N, C, G, E, L, J, N, A, Q, and M represents a five-membered cyclic ring structure, then said five-membered cyclic ring structure lacks a carbonyl group as part of the cyclic ring;

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provided that in Formula I when W is C=O and the moiety:



represents the structure:



where R^{30} and R^{31} are independently H, alkyl, alkenyl, aryl, aralkyl, aralkenyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, heterocyclyl, heterocyclylalkyl, heteroaryl or heteroarylalkyl, with R^{30} and R^{31} being optionally substituted with 1-3 R^{33} substituents selected from alkyl, aryl, aralkyl, alkoxy, aryloxy, aralkoxy, cycloalkyl, cycloalkoxy, heterocyclyl, heterocycliloxy, heterocyclylalkyl, keto, hydroxy, amino, alkylamino, alkanoylamino, aroylamino, aralkanoylamino, carboxy, carboxyalkyl, carboxamidoalkyl, halo, cyano, nitro, formyl, acetyl, sulfonyl, or sulfonamido, wherein said R^{33} substituents can be optionally substituted with alkyl, aryl, aralkyl, alkoxy, aryloxy, heterocyclyl, heterocycliloxy, keto, hydroxy, amino, alkanoylamino, aroylamino, carboxy, carboxyalkyl, carboxamidoalkyl, halo, cyano, nitro, formyl, sulfonyl or sulfonamido;

α is a bond, $-C(H)(R^{34})-$, $-O-$, $-S-$, or $-N(R^{35})-$, where R^{34} is H, alkyl, alkenyl, aryl, aralkyl, heterocyclyl,

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heterocyclylalkyl, heteroaryl, or heteroaralkyl and is optionally substituted with 1-3 R^{33} substituents, and R^{35} is H, alkyl, aryl, aralkyl, heterocyclyl, heterocyclylalkyl, heteroaryl, heteroaralkanoyl, $-C(O)R^{36}$, $-SO_2R^{36}$, or carboxamido and is optionally substituted with 1-3 R^{33} substituents, or R^{35} and γ together with the atoms to which they are bound, form a nitrogen containing mono- or bicyclic ring system optionally substituted with 1-3 R^{33} substituents, and R^{36} is alkyl, aryl, aralkyl, heterocyclyl, heterocyclylalkyl, heteroaryl or heteroaralkyl;

β is a bond, $-CH_2-$, $-C(O)-$, $-C(O)C(O)-$, $-S(O)-$, $-S(O)_2-$, OR $-S(O)R^{34}$;

γ is alkyl, alkenyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl, heterocyclyl, heterocyclylalkyl, heteroaryl, heteroaralkyl, $-OR^{37}$ or $-N(R^{37})_2$, wherein any carbon atom is optionally substituted with R^{33} , wherein R^{37} is independently H, alkyl, alkenyl, aryl, aralkyl, aralkenyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, heterocyclyl, heterocyclylalkyl, heterocyclylalkenyl, heteroaryl, or heteroaralkyl, wherein any carbon of R^{37} is optionally substituted with R^{33} ;

then R^{10} is H and R^8 and R^9 are independently selected from the group consisting of $CH(R^{1'})CONHCH(R^{2'})COOR^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})R'$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})COOR^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})COOR^{11}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})CONR^{12}R^{13}$, $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})CONHCH(R^{5'})COOR^{11}$ and $CH(R^{1'})CONHCH(R^{2'})CONHCH(R^{3'})CONHCH(R^{4'})CONHCH(R^{5'})CONR^{12}R^{13}$; and

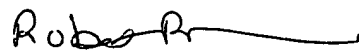
provided that the proline at the P2 position is modified, wherein the P2 position is the position corresponding to the second amino acid from the keto amide group.

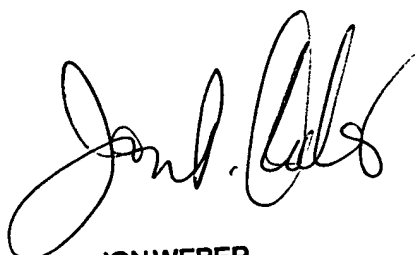
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi


08-31-05


JON WEBER
SUPERVISORY PATENT EXAMINER